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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/602,740	Applicant(s) POMPEJUS ET AL	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,9-14,17,25,26,28,29,31-33,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,9-14,17,25,26,28,29,31-33,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1, 4, 9-14, 17, 25, 26, 28, 29, 31-33, 39, and 40 are pending and under consideration in this Office Action.
2. The rejection of claims 12-14 under 35 USC 101 as being directed toward non-statutory subject matter has been withdrawn in view of applicants' amendment to the claims filed 03/22/2006, where the claims now encompass isolated host cells.
3. The rejection of claims 5, 6, 9-14, 17, 39 under 35 U.S.C. 112, first paragraph, as failing to meet the enablement requirement has been withdrawn in view of applicants' amendment to the claims and arguments filed 03/22/2006.
4. The Examiner acknowledges applicants' request of foreign priority in the amendment filed 06/30/2005. However, as stated in the previous Office Action no certified copies of the German patent applications have been received. Thus, as previously noted foreign priority is not granted.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1, 9-14, 17, 25, 26, 28, 29, 31-33, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claim 1 recites the phrase "less than about 5 kb of nucleotide sequences" which renders the claim vague and indefinite. The metes and bounds of the claim are not certain since the meaning of the phrase is not clear. It is uncertain whether 5 kb of nucleotide sequences actually flanks SEQ ID NO: 1.
No patentable weight is given to this limitation since the metes and bounds of the limitation are not known. The phrase "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of "less than about", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
Claims 9-14, 17, 25, 26, 28, 29, and 31-33 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

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Claim 40 recites the phrase "said nucleic acid molecule comprises less than about 4 kb, 3 kb, 2, kb, 1kb, 0.5 kb or 0.1 kb of nucleotide sequences" which renders the claim vague and indefinite. The metes and bounds of the claim are not certain since the meaning of the phrase is not clear.

No patentable weight is given to this limitation since the metes and bounds of the limitation are not known. The phrase "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of "less than about", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 9-14, 17, 25, 26, 28, 29, 31-33, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 as amended in the amendment file 03/22/2006 recites the following limitation:

"said nucleic acid molecule comprises less than about 5 kb of nucleotide sequence which naturally flank the nucleotide sequence of SEQ ID NO: 1".

Furthermore, claim 40 recites following limitation:

"said nucleic acid molecule comprises less than about 4 kb, 3 kb, 2, kb, 1kb, 0.5 kb or 0.1 kb of nucleotide sequences which naturally flank the nucleotide sequence of SEQ ID NO: 1 or the nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2".

According to MPEP § 2163.06:

"If new matter is added to the claims, the examiner should reject the claims under 35

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U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

The specification as originally filed does not disclose the above limitations and thus is considered new matter. Thus, the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 9-14, 17, 25, 26, 28, 29, and 31-33 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

9. Claims 25, 26, 28, 29, 31-33 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have not put forth arguments to address this ground of rejection. Thus, the rejection is maintained and reiterated below.

The nature and breadth of the claims encompass methods for making widely varying fine chemicals such as amino acids, nucleotides, aromatic compounds, vitamins, and proteins.

While the specification provides general guidance for transforming isolated *C. glutamicum* host cells with a vector containing the claimed isolated nucleic acid, the specification does not provide specific guidance, prediction, and working examples for any fine chemical that can be produced by culturing said isolated *C. glutamicum* host cells. Thus, an undue amount of trial and error experimentation must be preformed to search and screen for any fine chemical that can be produced by culturing the recited cell transformed with the claimed vector comprising the nucleotide sequence of SEQ ID NO: 1. Such experimentation is outside the realm of routine experimentation.

In view of the above considerations, the specification does not provide enablement for the claimed methods for making a widely varying fine chemicals such as amino acids, nucleotides, aromatic compounds, vitamins, and proteins.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 4, 9-14, 17, 25, 26, 28, 29, 31-33, 39, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Dunican et al. (US Patent 6,797,509).

Applicants' arguments filed 03/22/2006 have been fully considered but they are not persuasive. The examiner respectfully disagrees with applicants' position that Dunican et al. fail to teach the nucleic acid molecules encoding having 6-phosphogluconolactonase activity as recited in the amended claims.

For the reasons stated above in the rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite, no patentable weight is given to the phrases "less than about 5 kb of nucleotide sequences" and "said nucleic acid molecule comprises less than about 4 kb, 3 kb, 2, kb, 1kb, 0.5 kb or 0.1 kb of nucleotide sequences". Until the claims are amended, these limitations are not read into the amended claims. Thus, the claims are rejected for the reasons of record, which are reproduced below.

As stated in the previous Office Actions, Dunican et al. teach a 6995 base pair DNA sequence comprising that is 100% identical to SEQ ID NO: 1 of the claimed invention (see alignment attached to the Office Action dated 01/13/2005). The examiner takes the position that in absence of facts to the contrary the DNA taught by Dunican et al. would inherently encode a polypeptide having 6-phosphogluconolactonase activity since Dunican et al. teach a 6995 base pair DNA sequence that is 100% identical to SEQ ID NO: 1 of the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing the nucleic acid molecule comprising SEQ ID NO: 1 of the instant invention to the DNA sequence taught by Dunican et al., the burden is on applicants to show that the prior art DNA taught by Dunican et al. is different from the claimed nucleic acid molecule comprising SEQ ID NO: 1. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office

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action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER